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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

7590 05/22/2006

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/674,268	**Applicant(s)** FANTUZZI, MICHAEL	
	Examiner Rosanne Kosson	**Art Unit** 1653	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on April 28, 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see below.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

All of Applicant's arguments have been considered, but they are not persuasive. Applicant asserts that the claimed invention is not obvious because Erwin does not teach or suggest encapsulating a solution of co Q10 (coenzyme Q10) in limonene in a soft gel capsule, and one of ordinary skill in the art would have no expectation of success in doing so. Soft Gel does not teach, suggest or provide any expectation of success in selecting a monoterpene, such as limonene, as a carrier for any ingredient. Davidson et al. do not teach that co Q10 is soluble in fish oil and do not remedy the deficiencies of the other references. Limonene, rice bran oil, vitamin E and fish oil are chemically different in their makeup. Therefore, the prior art does not teach, suggest or provide any motivation or expectation of success in incorporating co Q10 dissolved in limonene in a soft gel capsule.

In reply, the rejection is not an anticipation rejection over Erwin or Soft Gel, but an obviousness rejection in view of three references, Erwin, Soft Gel and Davidson et al. As previously discussed, Erwin teaches dissolving co Q10 in limonene, Soft Gel teaches dissolving co Q10 in rice bran oil and formulating this solution as a soft gel capsule, and Davidson et al. teaches dissolving co Q10 in fish oil and formulating this solution as a soft gel capsule. It would have been obvious to one of ordinary skill in the art of medical chemistry or pharmacology at the time that the invention was made to encapsulate a solution of any therapeutic agent in a soft gel capsule, as this form of pharmaceutical formulation was well known at the time of Applicant's invention. Applicant did not invent soft gels. Thus, at the time of the invention, one of ordinary skill in the art would have had every expectation of success in formulating the co Q10-containing limonene solution of Erwin as a soft gel. Additionally, Soft Gel teaches that its soft gel rice bran oil formulation delivers more co Q10 to cells than other formulations, such as dry formulations or that of Folkers et al., in which co Q10 is dissolved in soybean oil (see Soft Gel, p. 2, lines 36-43). If co Q10 were insoluble in rice bran oil, it would not be delivered to cells, and the Soft Gel formulation would not achieve higher blood levels of co Q10 than that of Folkers et al. As previously discussed, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to formulate the composition of Erwin, in which co Q10 is dissolved in the plant oil limonene, as a soft gel capsule, because Soft Gel teaches that soft gel capsules are easily administered to humans and that when co Q10 is dissolved in a plant oil, such as rice bran oil, more of it is absorbed into the bloodstream, compared to dry capsules. As also previously discussed, one of ordinary skill in the art at the time that the invention was made would have been motivated to substitute the rice bran oil of Soft Gel with the limonene of Erwin as the solvent, because both have been shown to be pharmaceutically effective and acceptable solvents for co Q10. Applicant notes that the two solvents, limonene and rice bran oil, have different chemical structures. But, the solvents do not react chemically with co Q10, and both can be used to prepare solutions of coQ 10. Thus, as previously discussed, they may be used interchangeably. It is prima facie obvious to dissolve a compound in a solvent in which the compound is known to be soluble and to use a liquid vehicle for that compound which has been shown to be successful in formulating that compound.

Regarding Applicant's assertions that the solubility of co Q10 in limonene and that the encapsulation of co Q10 in a soft gel capsule are unexpected findings, as previously discussed, Erwin discloses that dissolving co Q10 in limonene improves its bioavailability (see paragraphs 2, 5, 6, 37, 38 and 40), and Soft Gel discloses that dissolving co Q10 in a plant oil and formulating it as a soft gel capsule provides a formulation of co Q10 that is easy to self-administer and one with improved bioavailability compared to earlier formulations. Applicant's claimed product, therefore, does not appear to have any aspects that are unexpected.

Applicant asserts that it is not proper to extract selectively individual elements from different references and then combine these elements to arrive at a claimed combination. The elements should be considered in the references as a whole because it is impermissible to pick and choose only so much as supports a given position. In reply, Applicant's point is not clear, as these comments are not specific to the rejection at hand. Nothing has been taken out of context and given an unintended meaning. Things out of context have not been pieced together for any purpose. Erwin and Soft Gel were cited for their main teachings, and Davidson et al. were cited in connection with claims that recite that the carrier is fish oil (claims 40 and 50).

In view of the foregoing, the rejection of record is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-05-11

Rosanne Kosson

Jon Weber
Supervisory Patent Examiner